MODULE 1311

CLEAN PROFESSIONAL INFORMATION

ISOPTO® ATROPINE 1 % Eye Drops

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SCHEDULING STATUS: **S 3**

1 NAME OF THE MEDICINE

ISOPTO® ATROPINE 1 % w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Atropine sulphate 10 mg per ml.

Preservative: benzalkonium chloride 0,01 % (mass/volume).

'For full list of excipients, see section 6.1'.

3 PHARMACEUTICAL FORM

Eye Drops Solution

A clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use as long acting mydriatic and cycloplegic.

4.2 Posology and method of administration

For ocular use only.

After cap is removed, if tamper evident snap collar is loose, remove it before using the product.

Care should be taken to avoid contact between the dropper tip and the eye, eyelashes or any other surface.

For refraction: Place one drop twice daily in the eye(s) for 1 to 2 days before examination, and 1 drop 1 hour before examination.

For uveitis: Place 1 drop in the eye(s) 3 times daily.

Systemic absorption may be minimised by compressing the lacrimal sac for a minute or two following instillation.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

The cap should be replaced tightly after use.

4.3 Contra-indications

ISOPTO® ATROPINE is contra indicated in patients with closed angle glaucoma or with a narrow angle between the iris and the cornea.

Hypersensitivity to the active ingredient, belladonna alkaloids, or to any of the excipients.

Children younger than 3 years.

4.4 Special warnings and precautions for use

Use with extreme caution, if at all, in children 12 years and above with

Down syndrome, spastic paralysis or brain damage.

It may increase intra ocular pressure, therefore mydriatics and cycloplegics should be used with caution in elderly and others where an increase may be encountered.

The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients.

Determine the intraocular pressure and an estimation of the depth of the angle of the anterior chamber prior to initiation of therapy to avoid glaucoma attacks.

Tonometric examination prior to drop instillation is advisable.

Use with caution in children and elderly patients, but reactions may occur at any age.

Patients may experience sensitivity to light and should protect their eyes in bright illumination.

Because of the risk of provoking hyperthermia ISOPTO ATROPINE should be used with caution in patents, especially children, who may be exposed to elevated environmental temperatures or who are febrile.

ISOPTO ATROPINE contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses.

Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to instillation and to wait at least 15 minutes before reinsertion.

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

4.5 Interaction with other medicines and other forms of Interaction

No interaction studies have been performed.

The effects of ISOPTO ATROPINE may be enhanced by concomitant use of other medicines having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics and tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Fertility

There is no adequate information on whether this medicine may affect fertility in males and females.

Pregnancy

Safety and efficacy has not been established.

Since it is not known whether topically administered atropine sulphate can cause foetal harm, ISOPTO® ATROPINE should not be used during pregnancy.

Lactation / Breastfeeding

It is unknown whether atropine is excreted in breast milk.

Traces of atropine have been found in human milk following administration of atropine solution for injection. Because some systemic absorption occurs from topical administration, caution should be exercised when ISOPTO® ATROPINE is administered to a nursing woman.

Effects on ability to drive and use machines

ISOPTO ATROPINE has a major influence on the ability to drive and use machines. ISOPTO ATROPINE may cause drowsiness, blurred vision and sensitivity to light. Patients should be advised not to drive or engage in other hazardous activities unless vision is clear.

4.8 Undesirable effects

The following side effects have been identified from post-marketing surveillance following administration of ISOPTO ATROPINE.

Frequency categories are defined according to the following convention:

Not known (cannot be estimated from the available data).

Within each System Organ Class adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	Frequency	Undesirable effects
Immune system disorders	Not known	hypersensitivity
Psychiatric disorders	Not known	hallucination, confused state, disorientation
Nervous system disorders	Not known	dizziness, headache
Eye disorders	Not known	eyelid oedema, photophobia, vision blurred, drug effect prolonged (mydriasis)

Cardiac Disorders	Not known	tachycardia, bradycardia
Gastrointestinal Disorders	Not known	intestinal obstruction, abdominal distention, vomiting
Skin and subcutaneous disorders	Not known	erythema, rash
General disorders and administration site conditions	Not known	pyrexia

Hypersensitivity to atropine is not uncommon and occurs as conjunctivitis.

Systemic toxicity may be produced by the instillation of anti cholinergic ophthalmic solution.

Atropine produces reactions similar to those of other anti cholinergic drugs. The central nervous system manifestations such as ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people are possible.

Other toxic manifestations of anticholinergic drugs are skin rash, unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility, and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages.

Severe reactions are manifested by hypotension with rapid progressive respiratory depression.

Symptoms of toxicity are usually transient (lasting a few hours), but may last up to 24 hours.

Prolonged use of mydriatics may produce local irritation characterized by conjunctivitis (follicular), ocular hyperaemia, eye oedema, eye discharge and eczema.

Paediatric population

Use of ISOPTO ATROPINE has been associated with psychotic reactions and behavioural changes in children.

Central nervous system reactions manifest similarly to those listed above.

ISOPTO ATROPINE can cause hyperpyrexia in children.

Increased risk for systemic toxicity has been observed in children with Down syndrome, spastic paralysis or brain damage with this class of drug.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Systemic toxicity may occur following topical use, particularly in children.

It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, convulsions and hallucinations and the loss of neuromuscular coordination. Severe intoxication

is characterized by central nervous system depression, coma, circulatory and respiratory failure and death.

Treatment is symptomatic and supportive.

Physostigmine salicylate 1 to 2 mg subcutaneously, I.M. or I.V. will control central and peripheral effects.

Excitement may be controlled by small doses of a short acting barbiturate such as thiopentone sodium 100 mg.

An ocular overdose can be flushed from the eye(s) with lukewarm water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC CODE: S01FA01

A.15.4 Ophthalmic preparations, other.

In ophthalmology atropine is used for mydriatic and cycloplegic effects.

Atropine sulphate blocks the action of certain parasympathetic nerves and cholinergic drugs.

Dilation of the pupils occurs in half an hour following its local application and lasts for a week or more. Accommodation is paralysed in 2 hours, with recovery in 2 or 3 days.

5.2 Pharmacokinetics

Atropine is readily absorbed from the gastro-intestinal tract and mucous membranes, it is also absorbed from the eye.

It is incompletely metabolised in the liver and is excreted in urine as unchanged and drug metabolites.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Boric acid

Methyl hydroxy propyl cellulose

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the container tightly closed.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

6.5 Nature and contents of container

Natural low density polyethylene bottle fitted with a natural dispensing

tip as plug and a liner-less red polypropylene cap and containing 5 ml.

6.6 Special precautions for disposal

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7 HOLDER OF CERTIFICATE OF REGISTRATION

Alcon Laboratories (SA) (Pty) Ltd

Magwa Crescent West

Jukskei View, Waterfall City, Johannesburg

2090

REGISTRATION NUMBERS

H.1135 (Act 101/1965)

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1 October 2004

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